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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,283	03/03/2004	Birke Bartosch	P08199US00/BAS	9764
881	7590	03/22/2006	EXAMINER	
STITES & HARBISON PLLC 1199 NORTH FAIRFAX STREET SUITE 900 ALEXANDRIA, VA 22314			CHEN, STACY BROWN	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/791,283

Applicant(s)

BARTOSCH ET AL.

Examiner

Stacy B. Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Applicant's amendment filed January 6, 2006 is acknowledged and entered. In the previous Office action mailed September 6, 2005, the examiner failed to indicate the fact that the restriction requirement is deemed proper and made FINAL. Claims 1-8 remain under examination. Claims 9 and 10 remain withdrawn from consideration because they are directed to non-elected subject matter.
2. Applicant's submission of an application data sheet (ADS) overcomes the objection to the declaration. The ADS has the full address of the first-named inventor, which was previously incomplete on the declaration that listed only a street address, but not the city or country.
3. The objection to claims 1-8 for failing to spell out acronyms at their first occurrence is withdrawn in view of Applicant's amendment. As for claim 1, the Office originally intended for Applicant to indicate that "E" represents envelope. However, upon further consideration, the requirement is not necessary.
4. The rejection of claims 1-8 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in view of Applicant's amendment to the claims.

### ***Claim Rejections - 35 USC § 103***

5. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marasco *et al.* (WO 00/55335 A1, "Marasco" in view of Schlapp *et al.* (EP 1170367 A1, "Schlapp") and Lai *et*

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*al. (J. Virology, 2000, 74(14):6339-6347, "Lai")*. Previously the claims were rejected over Marasco in view of Schlapp. In response to Applicant's amendment to the claims, the rejection now includes a new reference, Lai.

The claims are drawn to a method for producing pestivirus-like particles *ex vivo* comprising the steps of:

- Providing a first nucleic acid sequence comprising a packaging competent retroviral-derived genome;
- Providing a second nucleic acid sequence comprising a cDNA encoding core proteins from said retrovirus;
- Providing a third nucleic acid sequence comprising a cDNA encoding a polyprotein comprising successively a pestivirus core protein, and a E<sup>ms</sup> protein and/or pestivirus E1 protein and/or a pestivirus E2 protein, and optionally a pestivirus p7 protein;
- Transfecting host cells with said nucleic acid sequences and maintaining the transfected cells in culture for sufficient time to allow expression of the cDNAs to produce structural proteins from pestivirus and retrovirus;
- Cleaving the pestivirus core protein from the polyprotein and allowing the structural proteins to form virus-like particles which do not include the pestivirus core protein.

Specifically, the core proteins are from a retrovirus selected from the group consisting of MLV, ALV, RSV, MPMV, HIV-1, HIV-2, SIV, EIAV, CAEV and HFV. The E<sup>ms</sup>, E1 and E2 pestivirus proteins, and optionally p7 pestivirus protein are from the same pestivirus. The pestivirus is BCDV, SFV or BDV. Also claimed are the virus particles produced from the methods.

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Marasco teaches pseudotyped lentiviral vectors comprising:

- A first vector containing a lentiviral gag gene (core)
- A second vector containing an env gene (gp41/120)
- A lentiviral pol gene (reverse transcriptase) encoding a lentiviral pol protein on the first or second vectors, and
- A packaging vector containing a nucleic acid sequence encoding a desired molecule.

The env gene can be heterologous to the lentiviral pol protein, selected from a variety of viral sources, including pestiviruses among others (Marasco, claims 1-3). Lentiviruses include FIV, EIAV and HIV, for example (Marasco, claims 7-17). Marasco is silent on the use of pestivirus core and E<sup>ms</sup> protein. (Note that the instant claims do not require E1, E2 or p7.) However, Schlapp teaches BVDV virus-like particles comprising a BHV-1 genome backbone with BVDV (a pestivirus) proteins including N (core protein packages viral RNA to form the nucleocapsid, N protein), E<sup>ms</sup>, E1 and E2 (Schlapp, page 3, lines 9-25).

It would have been obvious to use the core and E<sup>ms</sup> genes in lieu of the lentiviral env gene of Marasco's method. One would have been motivated to use the nucleic acid of the core gene from pestivirus because core protein is the second protein in the polyprotein that is ultimately responsible for signaling the formation of the N protein. One would have been motivated to use E<sup>ms</sup> because Marasco teaches that pestivirus env proteins are useful in the invention (Marasco, page 6, second full paragraph, and claim 3). One would have had a reasonable expectation of success that the E<sup>ms</sup> and core proteins would have been functional in Marasco's vector system because core is responsible for signaling the formation of the

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nucleocapsid. The E<sup>ms</sup> protein is part of the envelope that is antigenic, thus functioning in the same manner as Marasco's suggested pestivirus envelope protein (pseudo particle).

Applicant's arguments have been carefully considered but fail to persuade. Regarding the new limitation of "cleaving the pestivirus core protein from the polyprotein and allowing the structural proteins to form virus-like particles which do not include the pestivirus core protein", one of ordinary skill in the art would expect that the core protein is cleaved from the polyprotein naturally. Lai teaches that the first virally encoded protein of the pestivirus polyprotein is a unique protease (Npro for N-terminal protease) that is responsible for a self-cleavage that releases the N terminus of the core protein (abstract). Given this knowledge, one of ordinary skill in the art would have entirely expected that the C protein is N-terminally truncated from the polyprotein by the Npro protease. Since the C protein is N-terminally cleaved, it is not expected to be present in the virus-like particles. In essence, Applicant's new limitation does not distinguish over the claimed invention because the cleavage of the core protein from the polyprotein is a naturally occurring event.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

### ***Conclusion***

6. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



Stacy B. Chen  
March 10, 2006



JAMES HOUSEL 3/19/06  
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